

CLAIMS

3-15 only 19-20

102
1. A method for obtaining a liquid sample for assessment and diagnosis of a condition of interest of the pharynx of a person in need of such assessment and diagnosis, comprising the steps of:

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1, 7, 16, 17, 18
21-25

- a) gargling with a measured amount of a fully characterized sampling liquid, causing said sampling liquid to be in contact with the lower aspects of the pharynx of the person;
- b) retrieving said sampling liquid for analysis by tilting the head of the person down over a collection container, opening the mouth, and allowing the sampling liquid to exit the open mouth, via gravity, directly into the collection container; and
- c) analyzing said retrieved sampling liquid directly in said collection container for the condition of interest.

2. The method for obtaining a liquid sample as defined in Claim 1, further comprising the steps of:

- a) first rinsing the mouth with water and expectorating in order to minimize contamination of the sampling liquid; and
- b) gargling with the sampling liquid for a period of at least 5 seconds, during which time the sampling liquid is in contact with the lower aspects of the pharynx.

3. The method for obtaining a liquid sample as defined in Claim 2, wherein the retrieved sampling liquid is analyzed by pH measurement.

4. The method for obtaining a liquid sample as defined in Claim 3, wherein the pH measurement is obtained by a technique selected from the group consisting of colorimetric indicator substance, pH meter and digital read device.

5. The method for obtaining a liquid sample as defined in Claim 4, wherein the measured pH of said retrieved sampling liquid is compared with specified pH values, to identify the presence of abnormal pharynx pH.

6. The method for obtaining a liquid sample as defined in Claim 5, wherein the detection and measurement of an abnormally acidic sampling liquid pH is correlated to the presence and degree of the physiological condition of gastroesophageal acid reflux, with the pH of the retrieved sampling liquid being a function of refluxed acid reaching the pharynx.

7. The method for obtaining a liquid sample as defined in Claim 6, wherein the sampling liquid used for gargling comprises about 5 ml water of known pH.

8. The method for obtaining a liquid sample as defined in Claim 7, wherein said water is tap, bottled or distilled water, or saline solution.

9. The method for obtaining a liquid sample as defined in Claim 8, wherein said collection container:

- a) is made of reusable, translucent, solid material;
- b) is of sufficient size to be held in the hand and to allow for collection of the sampling liquid as it falls from the mouth by gravity force, the container being held under the mouth with the head tilted forward; and
- c) has a horizontal marker to indicate adequate sampling liquid retrieval.

10. The method for obtaining a liquid sample as defined in Claim 9,
wherein said horizontal marker indicates a volume of at least 2 ml retrieved
sampling liquid.

11. The method for obtaining a liquid sample as defined in Claim 10, further including an interval period of about 30 minutes or more between last ingestion or oral hygiene activity and gargling with the sampling liquid.

12. The method for obtaining a liquid sample as defined in Claim 11, wherein the pH of said retrieved sampling liquid is determined by combining with said liquid an appropriate amount of a pH indicator selected from bromothymol blue, litmus powder and phenolphthazine-treated paper.

13. The method for obtaining a liquid sample as defined in Claim 12, wherein:

- a) the pH indicator is bromothymol blue solution with a pH scale of about 6.0 to 7.6 pH units, with distinct color intervals of 0.2 pH units or less;
- b) said bromothymol blue solution is added dropwise to said retrieved sampling liquid within said collection container followed by periodic light agitation of the collection container to ensure mixing of the pH indicator solution with the retrieved sampling liquid; and

c) the resulting color of the sampling liquid is observed after a suitable period of time from addition of the pH indicator solution, through said translucent collection container, to determine the pH of the sampling liquid by comparison of the observed color with a pH-color chart provided with the bromothymol blue solution.

14. The method for obtaining a liquid sample as defined in Claim 1, wherein the sampling liquid used for gargling comprises about 5 ml water of known pH.

15. The method for obtaining a liquid sample as defined in Claim 14, wherein said water is tap, bottled or distilled water, or saline solution.

16. The method for obtaining a liquid sample as defined in Claim 1, wherein the collection container:

a) is made of a reusable, translucent, solid material;

b) is of sufficient size to be held in the hand and to allow for collection of the sampling liquid as it falls from the mouth by gravity force, the container being held under the mouth with the head tilted forward; and

c) has a horizontal marker to indicate adequate sampling liquid retrieval.

17. The method for obtaining a liquid sample as defined in Claim 16, wherein said horizontal marker indicates a volume of at least 2 ml retrieved sampling liquid.

18. The method for obtaining a liquid sample as defined in Claim 2, further including an interval period of about 30 minutes or more between last ingestion or oral hygiene activity and gargling with the sampling liquid.

19. The method for obtaining a liquid sample as defined in Claim 4, wherein the pH of said retrieved sampling liquid is determined by combining with said liquid an appropriate amount of a pH indicator selected from bromothymol blue, litmus powder and phenolphthazine-treated paper.

20. The method for obtaining a liquid sample as defined in Claim 19, wherein:

- a) the pH indicator is bromothymol blue solution with a pH scale of about 6.0 to 7.6 pH units, with distinct color intervals of 0.2 pH units or less;
- b) said bromothymol blue solution is added dropwise to said retrieved sampling liquid within said collection container, followed by periodic

light agitation of the collection container to ensure mixing of the pH indicator solution with the retrieved sampling liquid; and

- c) the resulting color of the retrieved sampling liquid is observed after a suitable period of time from addition of the pH indicator solution, through said translucent collection container, to determine the pH of the sampling liquid by comparison of the observed color with a pH-color chart provided with the bromothymol blue solution.

21. A method for obtaining a liquid sample for assessment and diagnosis of a condition of interest of the mouth of a person in need of such assessment and diagnosis, comprising the steps of:

- a) rinsing the mouth with a specified amount of a fully characterized sampling liquid, causing said sampling liquid to be in contact with the mouth of the person;

b) retrieving said sampling liquid for analysis by tilting the head of the person down over a collection container, opening the mouth, and expectorating directly into the collection container; and

c) analyzing said retrieved sampling liquid directly in said collection container for the condition of interest.

22. The method for obtaining a liquid sample as defined in Claim 21, further comprising the steps of:

a) first rinsing the mouth with water and expectorating in order to minimize contamination of the sampling liquid; and

b) rinsing with the sampling liquid for a period of at least 5 seconds, during which time the sampling liquid is in contact with the mouth.

23. The method for obtaining a liquid sample as defined in Claim 22, wherein the sampling liquid comprises about 5 ml starting volume before rinsing.

24. The method for obtaining a liquid sample as defined in Claim 23, wherein the collection container:

- a) is made of reusable, translucent, solid material;
- b) is of sufficient size to be held in the hand and to allow for collection of the sampling liquid by expectoration, the container being held under the mouth with the head tilted forward; and
- c) has a horizontal marker to indicate adequate sampling liquid retrieval.

25. The method for obtaining a liquid sample as defined in Claim 24, wherein said horizontal marker indicates a volume of at least 2 ml retrieved sampling liquid.

26. A test kit for obtaining a liquid sample for assessment and diagnosis of a condition of interest of the pharynx of a person in need of such assessment and diagnosis, comprising:

- a) a hand-held, reusable article for measuring a diagnostic volume of a sampling liquid of known characteristics for gargling and deposition of said liquid into the back of the throat for gargling; and
- b) a container for depositing said sampling liquid after gargling, said container having a horizontal line provided thereon to serve as an indicator that an adequate volume of gargled sampling liquid was collected.

27. The test kit for obtaining a liquid sample as defined in Claim 26, further comprising diagnostic tools for identification of a characteristic of interest of the retrieved sampling liquid within the collection container at the time of sampling liquid retrieval.

28. The test kit for obtaining a liquid sample as defined in Claim 27, wherein said diagnostic tools measure the pH of the retrieved sampling liquid which can then be compared with specified values to identify abnormal pH of the retrieved sampling liquid which identifies the presence and degree of the physiological condition of gastroesophageal reflux.

29. The test kit for obtaining a liquid sample as defined in Claim 28, wherein said collection container:

a) is made of reusable, translucent, solid material,

- b) is of sufficient size to be held in the hand and to allow for collection of the sampling liquid as it falls from the mouth by gravity force, the container being held under the mouth with the head tilted forward; and
- c) has a horizontal marker to indicate adequate sampling liquid retrieval.

30. The test kit for obtaining a liquid sample as defined in Claim 29, wherein said horizontal marker indicates a volume of at least 2 ml retrieved sampling liquid.

31. The test kit for obtaining a liquid sample as defined in Claim 30, wherein the sampling liquid measuring article is spoon having a volume of about 5 ml.

32. The test kit for obtaining a liquid sample as defined in Claim 31, further comprising instructions for use as a self-test performed and interpreted by a layperson.

33. The test kit for obtaining a liquid sample as defined in Claim 31, further comprising instructions for use as a point-of-care test performed and interpreted by a physician.

34. The test kit for obtaining a liquid sample as defined in Claim 31, wherein a retrieved sampling liquid pH below 7.0, or which is 0.4 pH units or more lower than the individual's baseline, non-symptomatic sampling fluid pH, is considered to be indicative of acid reflux, with the level of sampling fluid acidity used to assess the degree of acid reflux.

35. The test kit for obtaining a liquid sample as defined in Claim 29, further comprising a container having therein a specified volume of said sampling liquid of known characteristics for gargling.

36. The test kit for obtaining a liquid sample as defined in Claim 29, wherein the sampling liquid used for gargling is tap water.

37. The test kit for obtaining a liquid sample as defined in Claim 35, wherein said sampling liquid is water, or a non-hazardous liquid, with a stable pH of about 7.4 to about 7.6, of sufficient volume to allow for a plurality of tests.

38. The test kit for obtaining a liquid sample as defined in Claim 29,
further comprising:

- a) a bottle of bromothymol blue pH indicator solution, where said solution is added in droplet form directly to the retrieved sampling liquid within the collection container and lightly agitated until a stable color is reached; and
- b) a pH color chart for comparison with the retrieved sampling liquid to indicate the pH of the retrieved sampling liquid.

39. The test kit for obtaining a liquid sample as defined in Claim 38, wherein the color chart for the pH indicator solution has a white area which can be placed behind the collection container as an aid in color recognition and comparison with the color chart.

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